



UNITED STATES PATENT AND TRADEMARK OFFICE

70.
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,058	10/17/2003	Kathryn F. Sykes	MCRO:003US	9509
32425	7590	02/02/2006	EXAMINER	
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,058

Applicant(s)

SYKES ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-51 is/are pending in the application.
- 4a) Of the above claim(s) 31-33,35-43, drawn to nonpolypeptide inventions is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,32,34 and 44-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 31-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 28 November 2005, is acknowledged. Applicants elect, without traverse, Invention II, claims 31, 32, 34, and 44-51, drawn to polypeptide compositions, classified in class 424, subclass 234.1.

Claims 31-33 and 35-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Applicants' Response to Election of Species is acknowledged. Applicants elect SEQ ID NO:8.

2. Claims 31, 32, 34, and 44-51 drawn solely to polypeptide compositions are under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 3, line 2, reference "Rouse, 1995" is not in the literature cited, pp. 106-111; line 5, reference "Ada, 1991" is not in the literature cited, pp. 106-111.

Page 6, line 21, reference "Steere et al., 2001" is not in the literature cited, pp. 106-111

Page 8, line 30, "LYMERix" should be "LYMERix",

Page 9, line 2, reference "Luft et al, 2002" is not in the literature cited, pp. 106-111,

Page 16, line 27, "Deer" should be "deer",

Page 18, line 6, "*Borrelia burgdorferi*" should be in italics,

Page 24, lines 19-26, "*Borrelia burgdorferi*" should be in italics,

Page 25, lines 1-3, 9-16, 21-22, and 27-31, "*Borrelia burgdorferi*" should be in italics,

Page 26, lines 1-3, 9-10, 16-23, and 29-31, "*Borrelia burgdorferi*" should be in italics,

Page 27, lines 1-3, 9-16, 22-23, and 28-30, "*Borrelia burgdorferi*" should be in italics,

Art Unit: 1645

Page 30, line 31, reference "Kaneda, 2000" is not in the literature cited, pp. 106-111

Page 31, lines 2-3, appear to be merely a copy of lines 1-2,

Page 33, line 19, reference "Kaneda, 2000" is not in the literature cited, pp. 106-111

Page 35, line 26, what is meant by ".",

Page 36, lines 7 and 19, what is meant by ".",

Page 50, lines 7 and 8, "polyepitop" should be "polyepitope",

Page 55, line 22, what is meant by "and ,"

Page 61, line 5, reference "Ol et al, 1986" is not in the literature cited, pp. 106-111; line

16, reference "Riechmann et al, 1988" is not in the literature cited, pp. 106-111

Page 81, line 30, "immunogeni" should be "immunogenic",

Page 95, line 2, reference "Potter et al., 2000" is not in the literature cited, pp. 106-111,

Page 96, lines 24, 25, 28, and 29, the names of the bacteria should be in italics,

Appropriate correction is required.

4. The attempt to incorporate subject matter into this application by reference to material merely recited as a name and a year is ineffective because the reference documents are not clearly identified as required by 37 CFR 1.57(b)(2).

Page 30, line 31, reference "Kaneda, 2000".

Page 33, line 19, reference "Kaneda, 2000".

Page 61, line 5, reference "Ol et al, 1986"; line 16, reference "Riechmann et al, 1988".

Because the documents are not clearly identified, as required by 37 CFR 1.57(b)(2), any attempt to amend the citation in order to reference a clearly identified document would constitute a "new matter" issue because the actual identity of the cited reference at the time of filing of the instant application is unknown.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 45, 46, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a composition comprising at least one or at least two or at least three or at least three "different" Borrelia antigens or fragment thereof.

It is unclear what is meant by "different". Does it mean that the antigens while unique from each other are from the same Borrelia species. Or does it mean that the antigens are from different species.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 31, 32, 34, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Alliger et al (U.S. Pat. No. 5,582,829, Dec. 1996).

Art Unit: 1645

The claims are drawn to a vaccine composition comprising at least one (claims 31, 32, 34, and 44), or at least two (claim 45) or at least three (claim 46) or at least four (claim 47) different *Borrelia* antigens or fragments thereof in a pharmaceutically acceptable carrier.

Allerger et al teach the claimed vaccine composition by teaching a vaccine composition comprising a sonicated preparation of at least two serovars of *B. burgdorferi* combined with a pharmaceutically acceptable carrier (Abstract; column 13, line 3 to column 14, line 24; claim 2). Since the preparation is the sonicate of whole bacteria, the preparation would comprise many different antigens present in the whole bacteria.

9. Claims 31, 32, 34, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergstrom et al (U.S. Pat. No. 5,688,512, Nov. 1997).

The claims are drawn to a vaccine composition comprising at least one (claims 31, 32, 34, and 44), or at least two (claim 45) or at least three (claim 46) or at least four (claim 47) different *Borrelia* antigens or fragments thereof in a pharmaceutically acceptable carrier.

Bergstrom et al teach the claimed vaccine composition by teaching a vaccine composition comprising substantially pure OspA from two or more strains of *B. burgdorferi* and an immunologically acceptable carrier (Abstract; claims 1 and 7) or a vaccine composition comprising fractions B, C, and or combinations thereof together with an immunologically acceptable carrier (column 16, line 5 to column 17, line 37).

10. Claims 31, 32, 34, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Lobet et al (U.S. Pat. No. 6,113,914, Sept. 2000).

The claims are drawn to a vaccine composition comprising at least one (claims 31, 32, 34, and 44), or at least two (claim 45) or at least three (claim 46) or at least four (claim 47) different *Borrelia* antigens or fragments thereof in a pharmaceutically acceptable carrier.

Art Unit: 1645

Lopet et al teach the claimed vaccine composition by teaching a vaccine composition comprising at least two purified OspA proteins from different *B. burgdorferi* subgroups I-VI in admixture with a suitable carrier (Abstract; example 6; claims 1-12).

11. Claims 31, 32, 34, and 44-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al (WO98/59071, Dec. 1998).

The claims are drawn to a vaccine composition comprising at least one (claims 31, 32, 34, 44, and 48), or at least two (claims 45 and 49) or at least three (claims 46 and 50) or at least four (claims 47 and 51) different *Borrelia* antigens or fragments thereof in a pharmaceutically acceptable carrier.

Choi et al teach the claimed vaccine composition combinations by teaching a vaccine composition comprising at least one or more *B. burgdorferi* polypeptides selected from a group consisting of four different peptide constructs (claim 16) in a pharmaceutically acceptable carrier. One of the whole peptides from which the constructs are formed, listed in Table 1 (f810.aa; page 134), is identical to the instantly claimed SEQ ID NO:8, and comprises a fragment of instantly claimed SEQ ID NO:6. Another whole peptide from which the constructs are formed as taught by Choi et al (f229.aa; page 169) is 98.2% identical to the instantly claimed SEQ ID NO:12.

Conclusion

12. No claims are allowed.

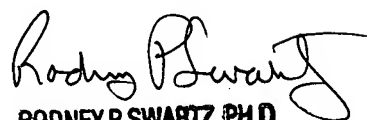
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

Art Unit: 1645

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

Art Unit 1645

January 30, 2006